



*YFW* 1646

PATENT  
Attorney Docket No. DALHO1270-2  
(028614-1001)

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Date of Deposit: March 1, 2004

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Stephen E. Reiter  
Printed Name

*Stephen E. Reiter*  
Signature

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Hoffman, Paul S. et al.

Serial No.: 09/647,661

Filing Date: January 31, 2001

For: NOVEL NITROREDUCTASE AND  
THERAPEUTIC USES THEREFOR

Examiner: Holleran, Anne L.

Group Art Unit: 1642

TRANSMITTAL

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Dear Sir:

Enclosed please find the following:

- ☒ Copy of Notice to Comply With Sequence Rules
- ☒ Amendment in Response to Notice Under 37 CFR §§1.821-825
- ☒ Statement to Support Filing and Submission in Accordance with 37 CFR §§1.821-825, and Sequence Listing Paper Copy
- ☒ Computer Disk Containing Sequence Listing
- ☒ Return postcard

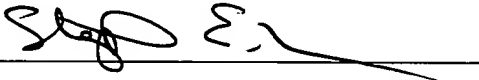
In re Application of Hoffman, Paul S. et al. Application No. 09/647,661 Page 2	PATENT Attorney Docket No. DALHO1270-2 (028614-1001)
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No fee is deemed necessary in connection with this paper. However, if any fee is required, the Commissioner is hereby authorized to charge any fees under 37 C.F.R. §§ 1.16, 1.17, and 1.21 that may be required by this transmittal, or to credit any overpayment, to Deposit Account No. 50-0872.

Respectfully submitted,

Date: March 1, 2004

FOLEY & LARDNER LLP  
Customer Number: 30542  
Telephone: (858) 847-6711  
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By 

Stephen E. Reiter  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/647,661	01/31/2001	Paul S Hoffman	DALHO 1270-2	2441

7590 01/28/2004

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EXAMINER

HOLLERAN, ANNE L

ART UNIT PAPER NUMBER

1642

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Due 2-28-04  
DD-7-28-04  
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I.P. DEPT.  
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# Notice to Comply With Sequence Rules

Application No.

09/647,661

Examiner

Anne Holle

Applicant(s)

HOFFMAN ET AL.

Art Unit

1642

## NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to these regulations, published at 1114 OG 29, May 15, 1990 and at 55 FR 8230, May 1, 1990.

☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☒ 3. A copy of the "Sequence Listing" in Computer Readable Form (CRF) has not been submitted as required by 37 C.F.R. 1.821(e).

☐ 4. A copy of the "Sequence Listing" in Computer Readable Form (CRF) has been submitted. However, the content of the CRF does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐ 5. The Computer Readable Form (CRF) that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute CRF must be submitted as required by 37 C.F.R. 1.825(d).

☐ 6. The paper copy of the "Sequence Listing" is not the same as the Computer Readable Form (CRF) of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐ 7. Other: \_\_\_\_\_

### Applicant Must Provide:

☒ An initial or substitute copy of the CRF "Sequence Listing".

☐ An initial or substitute **paper copy** of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and CRF copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

PatentIn Software Program Support (SIRA)

Technical Assistance.....703-287-0200

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Art Unit: 1642

1. Applicants' response to the restriction requirement (under lack of unity) is acknowledged. Applicants have elected group I, claims 1-6, 13-18, 14, 25, 28-31 with new claims 38-44), with traverse. The traversal is based on the argument that the prior art has not disclosed the nucleotide sequence of the preferred embodiment of the claimed nitroreductases. Applicants assert that the reference cited (Tomb et al) only discloses the entire genome of the *Helicobacter pylori*. However, a review shows that Tomb disclosed individual genes within the entire genome and identified the sequence corresponding that which encodes the invention nitroreductases. Therefore, the claimed inventions lack unity as defined under PCT Rule 13.1 and 13.2. The restriction requirement is proper and is therefore, made FINAL.

2. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

The application lacks a Computer Readable Form (CRF) of the sequence listing. Because the claims refer to a specific sequence that requires searching against computer databases, applicants must supply a CRF.

✓ APPLICANT IS GIVEN A ONE MONTH EXTENDABLE PERIOD WITHIN WHICH TO COMPLY WITH THE SEQUENCE RULES, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136. In no case may an applicant extend the period for response

Art Unit: 1642

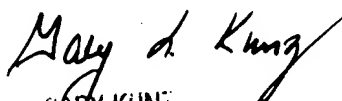
beyond the six month statutory period. Applicant is requested to return a copy of the attached Notice to Comply with the response.

Any inquiry concerning this communication should be directed to Examiner Holleran, Art Unit 1642, whose telephone number is (571) 272-0833.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D. can be reached at (571) 272-0871.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at telephone number (703) 308-0196.

Anne Holleran  
Patent Examiner  
January 23, 2004

  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600